

PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	10/056,597
(use as many sheets as necessary)				Filing Date	January 24, 2002
				First Named Inventor	Richard N. McArdle
				Art Unit	1761
				Examiner Name	
				Attorney Docket Number	876P167
Sheet	1	of	1		

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. 1	Document Number Number- Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		us-1,848,760	03-08-1932	W. W. Willison	
		us-2,556,579	06-12-1951	Forkner	
		us-2,578,915	12-18-1951	Bartels	
		us-3,224,869	12-21-1965	P. C. Keith et al	
		us-3,404,990	10-08-1968	Villadsen	
		us-3,557,085	01-19-1971	Douglas	
		us-3,558,598	01-26-1971	Epperson	
		us-4,248,142	02-03-1981	McKinney, Jr.	
		us-4,257,320	03-24-1981	Holbrook et al.	
		us-4,470,344	09-11-1984	Bushman	
		us-4,581,241	04-08-1986	DiCicca et al.	
		us-4,608,266	08-26-1986	Epperson et al.	
		us-4,647,466	03-03-1987	Japikse et al.	
		us-4,608,266	08-26-1986	Epperson et al.	
		us-4,876,102	10-24-1989	Feehley et al.	
		us-5,073,397	12-17-1991	Tarr et al.	
		us-5,108,774	04-28-1992	Mills et al.	
		us-			
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FOREIGN PATENT DOCUMENTS

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Nels R. Wolf

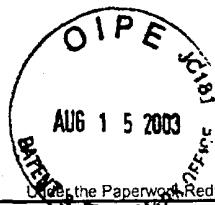
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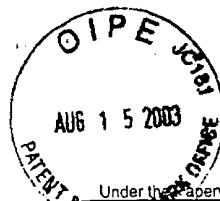
<p>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.</p> <p>TRADEMA Substitute for form 1449/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)</p>		<p>Complete if Known</p> <table border="1"> <tr> <td>Application Number</td> <td>10/056,597</td> </tr> <tr> <td>Filing Date</td> <td>January 24, 2002</td> </tr> <tr> <td>First Named Inventor</td> <td>Richard N. McArdle</td> </tr> <tr> <td>Art Unit</td> <td>1761</td> </tr> <tr> <td>Examiner Name</td> <td></td> </tr> <tr> <td>Attorney Docket Number</td> <td>0876-0167</td> </tr> </table>		Application Number	10/056,597	Filing Date	January 24, 2002	First Named Inventor	Richard N. McArdle	Art Unit	1761	Examiner Name		Attorney Docket Number	0876-0167
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Sheet	1	of	2												

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)			
<i>[Signature]</i>		WO 01/74181	10-11-2001	McArdle, et al.	

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Sheet	2	of	2
		Attorney Docket Number	

NON-PATENT LITERATURE DOCUMENTS

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JP	A	PCT International Search Report /	
JP	B	KEW T. J. ET AL.: "CITRUS PRODUCT COLOR ENHANCEMENT USING EXTRACTS / OF PEEL OF DIFFERENT VARIETIES"	
JP		Journal of Food Science, XX, XX, vol. 35, no. 4, 1970, pages 436-439, XP001041624.	
JP	C	WILSON C. W. ET AL.: "THREE TYPES OF CITRUS PEEL WASTE AS SOURCES OF COLOR", Journal of Food Science	
JP		XX, XX, vol. 36, no. 7, 1971, pages 1033-1035, XP001041625	
JP	D	TING S. V. ET AL.: "NATURAL COLOUR ENHANCERS - ORANGE PEEL / CAROTENOIDS FOR ORANGE JUICE PRODUCTS"	
JP		Food Technology, Institute of Food Technologists, Chicago, US, vol. 23, no. 7, 1969, pages 947-950,	
JP		XP002184128.	

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FORM PTO-1449 (Rev. 2032)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No.: 6483.US.C2	Serial No. : Not yet assigned
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant Barrett-Reis, et al.	
(Use several sheets if necessary)		Filing Date: August 13, 2002	Group:

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

✓		Mead Johnson & Company, Enfamil Your first choice just got better, LA3012 NEW 10/00, 2000.
✓		Porcelli, et al., "Growth in Human Milk-Fed Very Low Birth Weight Infants Receiving a New Human Milk Fortifier", Annals of Nutrition & Metabolism, 2000, 44:2-10.
✓		Franz, et al., "Prospective Randomized Trial of Early Versus Late Enteral Iron Supplementation in Infants With a Birth Weight of Less Than 1301 Grams", PEDIATRICS, Vol. 106, No. 4, October 2000, pages 700 - 706.
✓		Barrett Reis, et al., "Enhanced Growth of Preterm Infants Fed a New Powdered Human Milk Fortifier: A Randomized, Controlled Trial", PEDIATRICS, Vol. 106, No. 3, September 2000, pages 581 - 588.
✓		Mead Johnson Nutritional Division, Product Handbook Enfamil Human Milk Fortifier, L-B641-8-83
✓		Schanler, et al., "Fatty Acid Soaps May Be Responsible for Poor Fat Absorption in Premature Infants Fed Fortified human Milk (FHM)", Abstract No. 1707, Pediatric Research, April 1999, Vol. 45, No. 4, page 290A.
✓		Schanler, et al., "Postnatal attainment of intrauterine macromineral accretion rates in low birth weight infants fed fortified human milk", The Journal of Pediatrics, March 1995, pages 441 - 447.
✓		Porcelli, et al., "A New Human Milk Fortifier (HMF): A Multicenter Report", Pediatric Research, Abstract No. 200, Vol. 40, No. 3, 1996.
✓		Schanler, et al., "Fortified Human Milk Improves The Health Of The Premature Infant", Abstract No. 217, Pediatric Research , Vol. 40, No. 3, 1996.
✓		Fenton, et al., "Osmolality of Breast Milk Enriched with Added Formula Powders", Abstract No. 1657, Pediatric Research, April 1999, Vol. 45, No. 4, page 281A.
✓		Fenton, et al., "Comparison of Tolerance, Parental Attitudes and Duration of Breast Feeding with Powdered Versus Liquid Breast Milk Enrichment Products for Very Low Birth Weight Infants", Abstract No. 1658, Pediatric Research, April 1999, Vol. 45, No. 4, page 282A.
✓		Sankaran, et al., "A randomized, controlled evaluation of two commercially available human breast milk fortifiers in healthy preterm neonates", Journal of the American Dietetic Association, November 1996; 96 : 1145-1149.
✓		McNaught, et al., "An Evaluation of a New Human Milk Fortifier in Preterm Infants", Journal of Investigative Medicine, Vol. 48, Page 93A, January 2000.
✓		Lucas, et al., "Randomized outcome trial of human milk fortification and developmental outcome in preterm infants", Am J Clin Nutr 1996; 64 : 142-51.

EXAMINER <i>Adeleene Pratt</i>	DATE CONSIDERED <i>10-8-03</i>
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(Use several sheets if necessary)		Filing Date: August 13, 2002	Group:

10/21/92
08/13/02

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date (if appro.)
10	5,013,569	05/07/91	Rubin			
	4,692,340	09/1987	Grutte, et al.			
	4,753,926	06/1988	Lucas, et al.			
✓	6,136,858	10/2000	Kuchan, et al.			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Name	Class	Subclass	Translation (Yes No)
10	EP 0 799 577 A1		Shimamura, et al.			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	"Dictionnaire vidal", 1990, Editions De Vidal, Paris, XP002144922, page 100: materna complet.
10	Tönz, et al., "Die Ernährung kleiner Frühgeborener mit FMas: energie-,protein- und mineralienverstärkte Frauenmilch", Monatsschrift Fuer Kinderheilkunde, vol. 134, no. 12, 1986, pages 885-887, XP000933726.
10	Moyer-Miteur, et al., "Evaluation of Liquid or Powdered Fortification of Human Milk or Growth and Bone Mineralization Status of Preterm Infants", Journal of Pediatric Gastroenterology and Nutrition, vol. 15, no. 4, 1992, pages 370-374, XP000933692.
10	Voyer, et al., "Human Milk Lacto-Engineering: Growth Nitrogen Metabolism, and Energy Balance in Preterm Infants", ACTA Paediatrica Scandinavica, vol. 73, no. 3, 1984, pages 302-306, XP000933589.
10	Boehm, "Nitrogen and fat balances in very low birth weight infants fed human milk fortified with human milk or bovine milk protein", European Journal of Pediatrics, vol. 152, no. 3, 1993, pages 236-239, XP000929747.
10	Rönnholm, et al., "Human Milk Protein and Medium-Chain Triglyceride Oil Supplementation of Human Milk: Plasma Amino Acids in Very Low-Birth-Weight Infants", Pediatrics, vol. 74, no. 5, 1984, pages 792-799, XP000933587.
10	Raschko, et al., "Comparison of Fortified Human Milk (Using Similac Natural Care® With Experimental LBW Infant Formula", Pediatric Research, vol. 21, no. 4, Part 2, 1987, page 435A, XP000933586.
10	Bhatia, et al., "Human Milk Supplementation: Delivery of Energy, Calcium, Phosphorus, Magnesium, Copper, and Zinc", American Journal of Diseases of Children, vol. 142, no. 4, 1988, pages 445-447, XP000933462.

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

W		Barrett-Reis, et al., "An Evaluation of Growth and Serum Biochemistries of Preterm Infants Fed Preterm Human Milk Fortified with a New Powdered Human Milk Fortifier (PHMF)", Abstract 70, Journal of the American College of Nutrition, Vol. 18, No. 5, 539, page 62633, October 1999
		Moro, et al., "Fortification of Human Milk: Evaluation of a Novel Fortification Scheme and of a New Fortifier", Journal of Pediatric Gastroenterology and Nutrition, 20:162-172, 1995
		Schanler, et al., "Feeding Strategies for Premature Infants: Beneficial Outcomes of Feeding Fortified Human Milk Versus Preterm Formula", Pediatrics, Vol. 103, No. 6, 6 June 1999, pages 1150-1157
		Pediatric Nutrition Handbook Fourth Edition, Committee on Nutrition American Academy of Pediatrics, Ronald E. Kleinman, MD, editor, 1998, pages 55-87
		CRC Handbook of Chemistry and Physics A Ready-Reference Book of Chemical and Physical Data 79 th Edition, David R. Lide, Ph.D. editor, 1998-1999, pages 8-111 – 8-117, 4-35 – 4-47
		Williams and Chase, Methods in Immunology and Immunochemistry, Vol. II, 1968, pages 280 – 283
		Ehresmann, et al., "Spectrophotometric Determination of Protein Concentration in Cell Extracts Containing tRNA's and rRNA's", Analytical Biochemistry 54, 454-463 (1973)
		Cordle, et al., "Evaluation of the immunogenicity of protein hydrolysate formulas using laboratory animal hyperimmunization", Pediatric Allergy Immunol 1994; 5: 14-19
		Meeting the Special Nutrient Needs of Low-Birth-Weight and Premature-Infants with Similac [®] Human Milk Fortifier or Similac Natural Care [®] , Ross Products Division Abbott Laboratories, February 2000
		Enfamil [®] Human Milk Fortifier Label, Mead Johnson & Company, 1987
		Enfamil [®] Human Milk Fortifier Label, Mead Johnson & Company, 2000
		Davies, D.P., "Adequacy of expressed breast milk for early growth of preterm infants", Archives of Disease in Childhood, 52, p. 296-301, 1997
✓		Schanler, "Suitability of human milk for the low-birth weight infant", Clinics in Perinatology, 22, pp. 207-222, 1995

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